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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,762	12/28/2000	Kazuyuki Yanase	114474-14-FESI00002US	5214
38492 7590 03/05/2008 WILLKIE FARR & GALLAGHER LLP INTELLECTUAL PROPERTY LEGAL ASSISTANTS 787 SEVENTH AVE NEW YORK, NY 10019-6099				
EXAMINER				
HAMO, PATRICK				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/720,762

Applicant(s)

YANASE ET AL.

Examiner

PATRICK HAMO

Art Unit

3746

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6-9,11 and 13-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-9,11 and 13-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

This action is in response to amendments filed on January 8, 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6-9, 11 and 13-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation in independent claims 1, 9, 23 and 33 that "the restriction has a height at least one-third the length of the peripheral side surface" was not disclosed in the specification. The restriction was described as having a depth of about 0.05 to 1.0mm. No other dimensions are specifically addressed about the restriction and, while drawings are not necessarily interpreted as drawn to scale, there can be no inference drawn from the drawings that the restrictions were in fact at least one-third the length of the side surface. Applicant does disclose that the gasket has the dual properties of improving leak protection and preventing fine wrinkles from forming when the gasket is pushed along the cylinder, however there is no indication in the rest of the disclosure that to

achieve this requires specifically that the restriction has a height at least one-third the length of the peripheral side surface. The limitation above therefore is not being included in the prior art search as it is new matter.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 6-9, 16-28 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., 6,080,136 in view of Sudo et al., 5,009,646.

Trull, in figure 6, disclose a syringe gasket (70) wherein a peripheral side surface (80) of the gasket is in contact with an inner surface of the syringe barrel (60). A restriction and a tapered slant with a first and second plunger diameter (labeled by the examiner on Figure 6 attached to the end of this office action) is provided, and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered slant (also labeled by the examiner on Figure 6).

Trull does not teach that one or both of the peripheral side surfaces that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with polyethylene fluoride resin.

However, Sudo teaches a syringe gasket (2) coated (3) with a thermoplastic resin such as polyethylene (col. 2 lines 10-24) to provide sealing and lubrication while preventing contamination from liquid lubricants (col. 1 lines 48-55).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material of polyethylene, as taught by Sudo et al., in order to eliminate the need for a lubricant and serve as a protective sealant coating for the gasket.

With respect to the fact that Sudo teaches the coating for more than just the peripheral side surface, namely the top surface in contact with the pumped liquid as a sealant, it is brought to applicant's attention that the bottom surface is not coated. This surface is not coated because coating it with a lubricant or sealant is not required. The coating has two functions, namely to lubricate and to seal. For the side surface, both of these functions are utilized. For the top portion, only the function of sealant is being utilized. In the present application, the coating and its function (sealing) are removed from the top surface. This does not add patentable weight because it would have been obvious to omit the coating where the function attributed to the coating is not desired or required. See MPEP §2144.04(2)(a).

Furthermore, Trull does not teach that the first and second diameter of the tapered slant have a difference between about .5mm and about 5mm or that the gasket's inner diameter, its height, its first diameter, or its second diameter. With respect to the specified gasket dimensions in the claims 3, 6-8, 19, 21,22, and 24-28, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v.

Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

With respect to claim 9, a second tapered (see examiner's marked up Figure 6) slant is formed between the peripheral side surface of the gasket (70) that is in contact with an inner surface of the syringe barrel (60) and the restriction (see examiner's marked up Figure 6). The gasket tightly closing the liquid is an obvious requirement for the syringe to pump fluid properly. A recitation with respect to the material intended to be worked upon by a claimed apparatus, in this case a contrast medium, does not impose any structural limitations upon the claimed apparatus, which differentiates it from the prior art apparatus satisfying the structural limitations of the claims, as is the case here.

Claims 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1 and 9 above, and further in view of Akaike et al., 5,061,247.

The references as applied to claims 1 and 9 above teach all of the limitations substantially as claimed except for the following: the gasket being made integrally of a material with JIS hardness of 55 to 60.

However, Akaike et al., in column 5 lines 58-59, disclose, that a hardness of JIS of 20-85 is optimal for gaskets applied to syringe devices. This general range covers the applicants claimed range. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify references as applied to

claims 1 and 9 above with a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device. With respect to the specific range of JIS hardness 55 to 60, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136. Other than the range being preferred for presumably general optimum device function, the applicant has provided no criticality or unexpected or non-obvious advantage over choosing one this particular range. The coating taught by the prior art is integral in that the coating and the plunger coated form an integral plunger assembly.

Claims 11 and 13, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1 and 9 above, and further in view of Higashikawa, 5,830,193.

The references as applied to claims 1 and 9 above teach all of the limitations substantially as claimed except for the following: that the syringe includes a luer lock.

However, Higashikawa in Figure 1a-1c, 7a, and 7b, teaches that luer lock mechanisms (37, 30, 22) have been especially common in medical syringes (21) for mounting needles (32) - see column 7 line 49.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the references as applied to claims 1 and 9

above by incorporating the luer locking mechanism, as taught by Higashikawa, in order to allow for needle mounting.

Claims 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 in view of Vacca, 5,531,255.

The references as applied to claim 1 above teach all of the limitations substantially as claimed except for the following: that only wherein the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with silicon.

However, Vacca teaches that adding lubricant to a syringe improves its performance and that silicon is a suitable lubricant (col. 3, ll. 14-18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the references if claim 1 above with the silicon lubrication of Vacca in order to improve the performance of the syringe.

Response to Arguments

Applicant's arguments filed January 8, 2008 have been fully considered but they are not persuasive. The arguments were in regards to the claim limitation that the restriction was at least one-third of the peripheral side surface. As discussed above, this limitation constituted new matter. Therefore, the arguments are not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **PATRICK HAMO** whose telephone number is (571)272-3492. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Devon Kramer can be reached on 571-272-7118. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3746

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Devon C Kramer/
Supervisory Patent Examiner, Art
Unit 3683

PH